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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,939

10/17/2005

Yoshio Okamoto

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7590

09/22/2008

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EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

09/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,939	Applicant(s) OKAMOTO ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5, 7-11, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6 pgs / 11Oct2005, 05Feb2007, 22Oct2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is the national stage entry of PCT/JP04/05760, filed 22 Apr 2004; and claims benefit of foreign priority document JAPAN 2003-119710, filed 24 Apr 2003.

Currently an English language translation of this foreign priority document has not been made of the record.

Claims 1-14 are pending in the current application. Claims 14 and 15, drawn to a non-elected invention, are withdrawn. Claims 5 and 7-11, drawn to non-elected species, are withdrawn. Claims 1-4, 6, 12 and 13 are examined on the merits herein.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-13, in the reply filed on 02 Jun 2008 is acknowledged. The traversal is on the ground(s) that a search for the elected invention would necessarily entail a search for the non-elected invention. This is not found persuasive because the preamble of "A separating agent for enantiomeric isomers" is interpreted as a functional limitation. While search and examination is based on every term in the claims of the claimed invention, a search based on the structural limitations of the claims may identify a prior art structure that is capable of meeting the functional limitations of the invention as claimed. Therefore a search of the elected invention would not necessarily entail a thorough of the non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 02 Jun 2008.

Claims 5 and 7-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the election requirement in the reply filed on 02 Jun 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 12 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "R represents a substituted or unsubstituted aromatic group..." (emphasis added) Claims 2, 12 and 13 depend from claim 1 and incorporate all limitations therein, including the language "a substituted or unsubstituted aromatic group".

The specification discloses specific aryl substituents, for example hydrogen, a halogen, an alkyl group, etc. (page 7, lines 4-5), which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1-2 is(are) directed to encompass substituted aromatic groups, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these substituents meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and because chemical substituents are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim, and no limiting definition is provided for what substituents are encompassed by the phrase substituted aromatic group.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical

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structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See Vas-Cath at page 1115.)

The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability ... of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274,

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Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to “define an unknown by its binding affinity to another unknown” failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

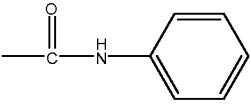
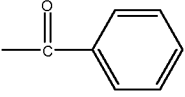
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

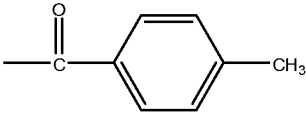
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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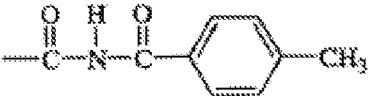
Claims 1-4, 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acemoglu et al. (Chirality, 1998, 10, p294–306, cited in PTO-892) in view of Okamoto et al. (Bull. Chem. Soc. Jpn. 1990, 63, 955-957, cited in PTO-892).

Acemoglu et al. teaches a separating agent for enantiomeric isomers comprising cellulose substituted with a combination of benzoate and aryl carbamate groups (page 294, left column, paragraph 2). Acemoglu et al. teaches the combination of aryl

carbamoyl, the group , and benzoate, the group , substituents (page 294, right column, paragraph 1). Acemoglu et al. teaches aryl group having different substitution patterns, for example 3,5-dimethylphenylcarbamoyl and 4-

methylbenzoyl, , groups (page 296, compound 6 of table 1).

Acemoglu et al. does not specifically disclose a separating agent for enantiomeric isomers comprising a polysaccharide substituted with a group represented

by the formula .

Okamoto et al. teaches the chiral recognition interaction of the phenylcarbamates of cellulose by hydrogen-bonding interactions of the NH and carbonyl groups of the phenylcarbamate group and by hydrogen bonding to the carbonyl of the carbamate

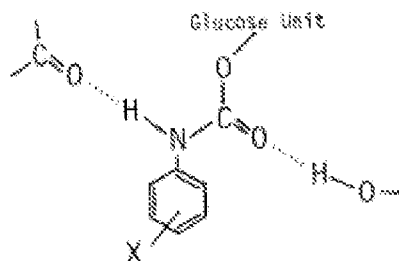


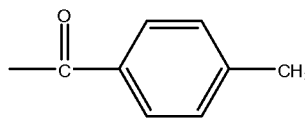
Fig. 2. Adsorbing site of phenylcarbamate derivatives.

(page 956, left

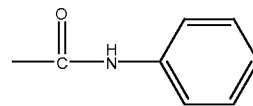
column paragraph 1 and right column, figure 2). Okamoto et al. teaches an electron withdrawing substituent, X, of the aryl ring enhances the hydrogen bonding between NH and a carbonyl group and that a change in the capacity factor may be associate with a change in the polarity of the urethane moiety.

It would have been obvious to one of ordinary skill in art at the time of the invention to combine the teaching of Acemoglu et al. in view of Okamoto et al. Both Acemoglu et al. and Okamoto et al. are drawn to the field of aryl-substituted cellulose as a separating agent. Acemoglu et al. teaches the aryl group attached to the by a

carbonyl functional group in the 4-methylbenzoyl substituent,

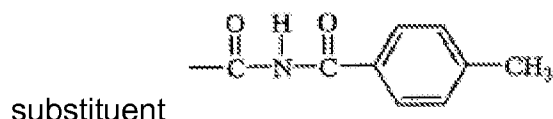


a -(O=)C-NH- group in the phenylcarbamoyl substituent,



, are functional groups that are known in the prior art as equivalents known for the same purpose of attaching an aryl group to a cellulose separating agent. It would have been obvious to one of ordinary skill in the art to combine the functional groups to give the

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. One of ordinary skill in the art would be motivated to combine the teaching of Acemoglu et al. in view of Okamoto et al. because Okamoto et al. teaches an electron withdrawing substituent, X, of the aryl ring enhances the hydrogen bonding between NH and a carbonyl group and that a change in the capacity factor may be associated with a change in the polarity of the urethane moiety. One of ordinary skill in the art would understand that the electron withdrawn effect of the substituent on the aryl group is transmitted by resonance to the NH group and would understand that an electron withdrawn group, such as a carbonyl group, attached to the NH would have an increased effect, as well as changing the polarity of the substituent.

Claim 13 recites "The separating agent for enantiomeric isomers according to claim 1, which is used as a stationary phase for continuous liquid chromatography". The phrase "which is used as a stationary phase for continuous liquid chromatography" is interpreted as a functional limitation of the claimed separating agent. It is apparent from what is disclosed that the separating agent taught by Acemoglu et al. in view of Okamoto et al. is capable of performing the function of being used as a stationary phase for continuous liquid chromatography.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

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3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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